

IN THE
United States Court of Appeals for the Eighth Circuit

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff-Appellant,

v.

CATHERINE HANAWAY, in her official capacity as Attorney General of the State of Missouri; JAMES L. GRAY, in his official capacity as President of the Missouri Board of Pharmacy; CHRISTIAN S. TADRUS, in his official capacity as Vice President of the Missouri Board of Pharmacy; DOUGLAS R. LANG, in his official capacity as a member of the Missouri Board of Pharmacy; COLBY GROVE, in his official capacity as a member of the Missouri Board of Pharmacy; ANITA K. PARRAN, in her official capacity as a member of the Missouri Board of Pharmacy; TAMMY THOMPSON, in her official capacity as a member of the Missouri Board of Pharmacy; and DARREN HARRIS, in his official capacity as a member of the Missouri Board of Pharmacy,

Defendants-Appellees,

—and—

MISSOURI HOSPITAL ASSOCIATION and MISSOURI PRIMARY CARE ASSOCIATION,

Intervenors-Appellees.

On Appeal from the United States District Court for the Western District of Missouri

2:24-cv-04131-MDH

The Honorable M. Douglas Harpool

PLAINTIFF-APPELLANT’S UNOPPOSED MOTION FOR JUDICIAL NOTICE

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November 12, 2025

Counsel for Plaintiff-Appellant

1. Plaintiff-Appellant Novartis Pharmaceuticals Corporation respectfully requests that the Court take judicial notice of the June 9, 2025 decision issued by the Health Resources and Services Administration (HRSA) regarding ADR ID: 230925-17. Novartis referenced this decision on pages 4-5 of its Reply Brief and has attached a copy of the decision letter to this motion.

2. In this decision, HRSA found that the federal 340B Program permits Novartis to apply its contract pharmacy policy to restrict covered entities' purchases of Novartis's drugs at 340B discounted prices. Petitioners, two covered entities from Washington State, asserted claims through HRSA's Administrative Dispute Resolution process alleging that Novartis's contract pharmacy policy unlawfully resulted in overcharges. *See University of Wash. v. Novartis Pharms. Corp.*, Case No. 230925-17 (Administrative Dispute Resolution, June 9, 2025). Petitioners asked the ADR Panel to order Novartis to end its policy limiting contract pharmacies to those located within 40 miles of the covered entity.¹ Novartis opposed and sought to dismiss the petition, explaining that the 340B Program allows manufacturers to impose reasonable conditions on the sale of 340B-priced drugs—such as limitations on contract pharmacies. HRSA agreed

¹ Novartis has since changed the terms of its contract pharmacy policy. The current policy limits covered entities without an in-house pharmacy to a single contract pharmacy. Opening Br. at 18 n.1; *see also Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 463-464 (D.C. Cir. 2024).

with Novartis, found its contract pharmacy policy lawful, and dismissed the covered entities' claims. *Id.*

3. Although HRSA is supposed to publish its final ADR decisions to its website within 120 days of issuance, 89 Fed. Reg. 28,643, 28,654 (April 19, 2024), the agency has not posted its decision to date, *see* HRSA, *ADR Decision Summaries*, <https://tinyurl.com/4vtwjy2k> (last updated May 15, 2025).

4. This Court has recognized that it may take judicial notice of matters “that are part of the public record,” *Miller v. Redwood Toxicology Lab’y, Inc.*, 688 F.3d 928, 931 (8th Cir. 2012), including any agency “order or rule issued ... pursuant to its delegated authority,” *Arkla Expl. Co. v. Texas Oil & Gas Corp.*, 734 F.2d 347, 361 n.22 (8th Cir. 1984). It has accordingly taken judicial notice of agency action in the past. *See, e.g., Arkla*, 734 F.2d at 361 (agency instruction memorandum); *Dionne v. Shalala*, 209 F.3d 705, 709 & n.2 (8th Cir. 2000) (agency publication regarding hiring qualifications); *Cunningham v. Apfel*, 222 F.3d 496, 500 n.4 (8th Cir. 2000) (agency award of benefits).

5. Judicial notice is particularly appropriate here because HRSA’s decision goes to the heart of this case. HRSA’s conclusion confirms that the federal 340B statute grants manufacturers discretion to limit the use of contract pharmacies and vests HRSA with exclusive authority to resolve disputes regarding these policies. *See also* 42 C.F.R. § 10.21(a)(1) (HRSA to decide “claims that a

manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price"). Missouri's attempt to insert itself in this process obstructs Congress's intent to create a "a uniform, nationwide" 340B enforcement mechanism in which HRSA would "hold the control rein." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 120 (2011).

6. Novartis conferred with counsel for the Appellees and Intervenor-Appellees who do not oppose this motion.

For the foregoing reasons, this motion for judicial notice should be granted.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 27(d)(2)(A) because it contains 556 words.
2. This brief complies with the typeface requirements of Fed. R. App. P. 27(d) and the type style requirements of Fed. R. App. P. 32(a)(5)-(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office 365 in Times New Roman 14-point font.
3. The electronic version of this brief has been scanned for viruses and has been found to be virus free.

/s/ Jessica L. Ellsworth
Jessica L. Ellsworth

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the Court's CM/ECF system on November 12, 2025. All counsel of record are registered CM/ECF users, and service will be accomplished by the CM/ECF system.

/s/ Jessica L. Ellsworth
Jessica L. Ellsworth